I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4).

Dated: October 26, 2011 Signature: /David A. Gass #38,153/ (David A. Gass)

Docket No.: 28113/39467A (PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Kari Alitalo et al.

Application No.: 10/567,630
Projected Patent No.: 8,029,984

Confirmation No.: 2853

Filed: May 30, 2006
Allowed: May 16, 2011
Projected Issue date: October 4, 2011

Art Unit: 1634

For: MATERIALS AND METHODS FOR COLORECTAL CANCER SCREENING, DIAGNOSIS, AND THERAPY

Examiner: S. T. Kapushoc

REQUEST FOR RECONSIDERATION OF PETITION DECISION ON APPLICATION FOR PATENT TERM ADJUSTMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The Applicants request reconsideration of the Office's Decision on Application for Patent Term Adjustment (PTA) mailed August 26, 2011 (hereinafter "the Decision") in connection with the above-referenced patent application/patent. The Director is authorized to charge any necessary fees due with this request to Deposit Account No. 13-2855, under order No. 28113/39467A.

I. Brief Review of Relevant Facts

Julie Burke, a supervisory patent examiner (SPE) and technology center quality assurance specialist (QAS), vacated (i.e., "made legally void," as defined in Merriam Webster's Collegiate Dictionary, 10th Edition, and Black's Law Dictionary, Ninth Edition; see Exhibit A) four improper restriction requirements (from January 15, 2008 to July 31, 2009, from three different examiners) and subsequently transferred the application to a fourth patent examiner who issued a

combined Restriction Requirement and Office Action on the merits on January 21, 2010. The *quality assurance specialist* determined that these first four actions were so deficient that they should be "vacated from the record and should not be used to calculate applicants Patent Term Adjustment." The Office has ignored the judgment of the SPE/QAS and used the date of the first *vacated* action for PTA calculation, *dismissing* Applicant's Application for Patent Term Adjustment dated August 16, 2011, and depriving the Applicants of 840 days of PTA (before consideration of "B" delay and A/B overlap).

II. Errors in the Office's Decision to Dismiss

The statutory purpose of the Patent Term Adjustment legislation was to guarantee the term of an applicant's patent against loss due to Patent and Trademark Office delays. Section 154(b)(1)(A) "Guarantee of Prompt Patent and Trademark Office Responses" and 37 CFR 1.703(a)(1) require extending the patent term if a notification under section 132 of the statute (or allowance) is not provided within 14 months.

A. The Decision erred on the date of the first action under 35 USC 132.

Unquestionably, a supervisory patent examiner who has been appointed as technology center quality assurance specialist is among the most experienced and qualified persons at the PTO to determine when an examiner within the technology center has issued a *bona fide* first action in applications assigned to that technology center. In this application, three different examiners issued four successive "restriction requirements." Julie Burke, a SPE and QAS for TC1600, *vacated* these actions and assigned the application to a *fourth* examiner, concluding that the first three examiners had entirely failed to further prosecution, and that a fresh start was necessary. By concluding that these four actions should be "vacated from the record and should not be used to calculate applicants Patent Term Adjustment," and assigning the application to new Office personnel, the quality assurance specialist made a determination on the record that her technology center had failed, in its first four tries, to issue a restriction requirement meeting minimum standards to qualify as a "notification" or "action" under 35 USC 132. The Office had done nothing to further prosecution of the application. Her evaluation of the prosecution should be dispositive.

The Decision states, "The Office notes that the Supervisory Patent Examiner was without authority to make a determination that the Restriction Requirements should not be used to

calculate Patent Term Adjustment." Respectfully, the relevant question is not who has authority to determine what action should be used for Patent Term Adjustment. Rather, the relevant question of *fact* is when the Office issued a *bona fide* first action under 35 USC 132 in the application; and the relevant question of *authority* is who is the proper judge of what "action" was a *bona fide* first action. The SPE/QAS from TC1600 is qualified to make the determination of whether or not a paper issued by an examiner is a *bona fide* fist action from the technology center, or fatally defective.[1] The Decision has erred by substituting the judgment of a Senior Petitions Attorney for that of the technology center SPE/QAS on whether a paper is a *bona* fide first action that meets the minimum standards of the Technology Center in which the SPE/QAS practices. The Decision appears to have been based on the *superficial* observation that a paper dated January 15, 2008, is *captioned in a computer system* as a "Requirement for Restriction" in the image file wrapper, with complete disregard to TC1600's evaluation that the paper was devoid of merit, and not a *bona fide* first action.

The Decision further states, "The record of the above-identified application indisputably indicates that the USPTO mailed a notification under 35 U.S.C. 132 in the form of a Restriction Requirement on January 15, 2008." The Applicants respectfully dispute this assessment. In the opinion of a SPE/QAS, memorialized in the written record of the application on September 2, 2009, and November 23, 2009, no *bona fide* first action had been issued as of those dates, notwithstanding four tries by three different examiners. Thus, the record "indisputably indicates" that **a supervisor in the technology center did NOT believe that the Applicants had received a *bona fide* first action**; that the SPE/QAS apologized to the applicants; and that the first four papers were vacated. The Decision's characterization of the record ignores the *substance* of the record. The judgment found in the record of the SPE/QAS who reviewed the substance of the papers record should be dispositive of when a *bona fide* first action was issued.

B. The Decision erred with respect to the legal effect of *vacatur.*

Even if, for the sake of argument, any of the first four "restriction requirements" had met the threshold level of quality to be a first action/notification under 35 USC 132, the fact remains that each of these actions was *vacated.* The established legal definition of *vacate* means that the

[1] Even if the SPE/QAS should have consulted a TC1600 director, there is no indication in the record that the SPE/QAS failed to follow normal protocols before reaching her decision. It is erroneous to conclude from the current record that proper procedure was not followed by the SPE/QAS.

actions were *void, with no legal effect*. (See Exhibit A.) The Office has ignored this established meaning, and substituted its own unique meaning in the Decision: *no legal effect except for purposes of 35 USC 154(b)(1)(A)*. No legal authority for this proposition was cited in the Decision, and it is clear error.

The Decision asserts that "The mere fact that an examiner or other USPTO employee upon further reflection determines that an Office action, or than a rejection, objection or requirement in an Office action, is not correct and must be removed does not warrant treating the Office action as void *ab initio* as if the USPTO had never issued the Office action." Even if this reasoning is sound, it does not describe the prosecution history of this case. Had there simply been a determination that previous positions were not correct, then the Office would have simply *withdrawn* its restriction requirements, and examination would have proceeded with the first examiner, or with the second examiner, or with the third examiner assigned to the case. Here, however, the determination was that the first three examiners had done nothing to further prosecution, warranting *vacatur* and transfer to yet a fourth examiner. Because the technology center quality assurance specialist vacated the actions on the record, and transferred the application to a fourth patent examiner, there is incontrovertible evidence on the record that the first four actions were vacated because they failed to satisfy the Office's minimum requirements for an action under 35 USC 132.

For the foregoing reasons, Applicants respectfully request reconsideration of the Decision and recalculation of the PTA as set forth in Applicants' initial request for reconsideration of PTA calculation dated August 16, 2011, incorporated herein by reference.

III. Miscellaneous issues

The Applicants' request dated August 16 preceded the Office's determination of "B delay." While this paper is a request for reconsideration of that request, the Applicants provide the following additional information for completeness. The Office has now determined that "B delay" of 668 days accrued from after 2-08-09 until 12-08-10. If Applicant's request is given favorable reconsideration, then "A delay" awarded to the Applicant *on account of a delayed first action* is 906 days (from July 30, 2007, to January 21, 2010). Under this corrected scenario, "A delay" and "B delay" overlap occurred from 2-08-09 through 1-21-10, or 347 days.

Thus, total A delay: 906 + 37 = 943; B delay: 668; (A+B)= 1611

Applicant delay: 60 days; A/B overlap: 347 days

Corrected PTA: 1611 – 60 - 347= 1204 days

Issuance of a certificate of correction with the corrected PTA is respectfully requested.

Dated: October 26, 2011

Respectfully submitted,

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